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EXAMINER	
LARKIN, DANIEL SEAN	

ART UNIT	PAPER NUMBER
2856	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,838	BLASCHKE ET AL.	
	Examiner	Art Unit	
	DANIEL S. LARKIN	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-17 and 27* is/are allowed.

6)☒ Claim(s) *18-26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on 29 August 2008. These drawings are acceptable.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 28 -30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention.

Re claim 28, claim line 8: The phrase "said at least one test region" lacks antecedent basis.

Re claim 30, claim line 9: The phrase "said at least one test region" lacks antecedent basis.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 03/012421 (Yoshida et al.).

With respect to the limitations of claims 25 and 26, Yoshida et al. disclose a biosensor, comprising: a base layer (3); an electrode layer supported by the base layer, the electrode layer having a first electrode (31) and a second electrode (32), the first and second electrodes respectfully extending from first and second electrode leads (32) and having central portions; a cover layer (4) disposed above the electrode layer, the cover layer having a projection (40) defining a sample cavity; a fluid inlet area (42) in fluid communication with said sample cavity; and first and second vents (51-53), the first vent (51) having a first guide edge and the second vent (52) having a second guide edge opposing the first guide edge, the first and second guide edges opposing each other above at least one of the central portions of the first and second electrodes. Additionally, the electrodes have central portions, an intermediate area between said first and second opposing guide edges being disposed above one of the central portions of the electrodes.

6. Claims 18-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,120,420 (Nankai et al.).

With respect to the limitations of claim 18, Nankai et al. disclose a biosensor, comprising: a sample cavity (8) for accepting sample fluid, the sample cavity having an fluid inlet (10); first and second vents (13, 12) within the sample cavity, the first and

second vents having respective first and second vent edges and being disposed along a fluid pathway of the sample cavity such that the first vent (13) is closer to the fluid inlet (10) than the second vent is; a first reagent area disposed along the sample cavity beneath said first vent (13), col. 8, lines 11-14; and a second reagent area disposed along the sample cavity beneath the second vent (12), col. 8, lines 11-14.

Nankai et al. further disclose that the first and second vents (13, 12) are spaced along the fluid pathway such that sample fluid entering the fluid inlet (10) contacts the first and second vent edges in succession, CLAIM 19. Additionally, the sensor is designed whereby the first reagent is adapted to react with the sample fluid for a first optimum reaction time and the second reagent is adapted to react with the sample fluid for a second optimum reaction time, the second optimum reaction time being less than the first optimum reaction time, CLAIM 20, because the a sample fluid must travel a tortuous path prior to reaching the vents. Nankai et al. also disclose an additional vent (11) having vent edges and being disposed along said fluid pathway, CLAIM 21, and additional reagent areas disposed along the sample cavities respectively beneath the additional vent, CLAIM 22, col. 8, lines 11-14.

With respect to the limitations of claims 23 and 24, Nankai et al. disclose a method for analyzing a fluid sample, comprising: accepting said sample fluid within a sample cavity via capillary action, the sample cavity having a fluid inlet (10) and first and second vents (11-13) disposed along a fluid pathway, the sample cavity further having a first reagent disposed beneath said first vent and a second reagent disposed beneath said second vent, col. 8, lines 11-14; the first and second vents having first and second

vent edges; guiding said fluid sample along said fluid pathway via capillary action such that the fluid passes the first vent before passing the second vent; and filling the sample cavity (8) such that the sample fluid first fills a first volume beneath the first vent and later fills a second volume beneath the second vent. Nankai appears to provide a time delay between the time at which the sample fluid fills the first volume beneath the first vent and the time at which the sample fluid fills the second volume beneath the second vent is greater than about three seconds, by providing a tortuous path for the sample fluid to flow in order to reach each vent.

With respect to the limitations of claims 25 and 26, Nankai et al. disclose a biosensor, comprising: a base layer (1); an electrode layer supported by the base layer, the electrode layer having a first electrode (41) and a second electrode (42), the first and second electrodes respectfully extending from first and second electrode leads (21, 22) and having central portions; a cover layer (7) disposed above the electrode layer, the cover layer having a projection defining a sample cavity (8, 81, 82); a fluid inlet area (10) in fluid communication with said sample cavity; and first and second vents (11-13, or 11, 12), the first vent (11) having a first guide edge and the second vent (12) having a second guide edge opposing the first guide edge, the first and second guide edges opposing each other above at least one of the central portions of the first and second electrodes. Additionally, the electrodes have central portions, an intermediate area between said first and second opposing guide edges being disposed above one of the central portions of the electrodes.

Response to Arguments

7. Applicants' arguments filed 29 August 2008 have been fully considered but they are not persuasive.

With respect to Applicants' argument, page 12, lines 9-12, that Yoshida et al. fail to disclose "a first vent having a first sample guide edge and said second vent having a second sample guide edge opposing said first sample guide edge, said first and second sample guide edges opposing each other above at least one of said central portions of said first and second electrodes", the examiner respectfully disagrees. Yoshida et al. show in the figures first and second vents (51-53), the first vent (51) having a first sample guide edge and the second vent (52) having a second sample guide edge opposing the first guide edge, the first and second sample guide edges opposing each other above at least one of the central portions of the first and second electrodes. Figure 4 also shows the vents (51-53) being directly above a central portion of the electrodes (33-35). Moreover, Applicants' argument with respect to Yoshida et al., page 12, lines 12-15, may be true; however, the operability of the guide edges as argued by Applicants does not matter since the functionality of the guide edges of the first and second vents is not present within the limitations recited in claims 25 and 26.

With respect to Applicants' argument, page 12, lines 26-30, and page 13, lines that Nankai et al. fail to disclose the limitation recited in the argument, the examiner disagrees; however, the examiner argues that the limitation recited by Applicants is not found within claim 18; and thus cannot be argued by the examiner with respect to Nankai et al. and in combination with all of the remaining limitations recited in claim 18.,

With respect to Applicants' argument, page 13, lines 12-14, that Nankai et al. fail to disclose that the discharge ports/vents guide the fluid sample along a fluid pathway such that the fluid passes the first vent before passing the second vent, the examiner agrees with Applicants' position but also notes that this limitation/feature is not found within the limitations of claim 18. No functionality for the vents has been set forth within the limitations present in claim 18. Since the above limitation is not found in the claims, the examiner cannot further comment with respect to Nankai et al.

With respect to Applicants' argument, page 13, lines 19-21, that Nankai et al. fail to disclose that the discharge ports/vents guide the fluid sample along a fluid pathway such that the fluid passes the first vent before passing the second vent, the examiner agrees with Applicants' position but also notes that this limitation/feature is not found within the limitations of claim 23. No functionality for the vents has been set forth within the limitations present in claim 23. Since the above limitation is not found in the claims, the examiner cannot further comment with respect to Nankai et al.

With respect to Applicants' argument, page 13, lines 11-12 and 17-19, that no portion of the discharge port disclosed in Nankai et al. provides the sample guide edges recited within claim 25, the examiner respectfully disagrees. Nankai et al. show that the discharge ports have edges and are directly located above the central portions of the electrodes. Applicants appear to "suggest" that the guide edges of the vents perform some function without claiming the specific function. Claim 25 as currently written only recites a vent having sample guide edges, which only means a vent having edging since the intended guiding functionality has not been expressly recited.

Allowable Subject Matter

8. Claims 1-17 and 27 are allowed.

9. Claims 28-30 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

10. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL S. LARKIN whose telephone number is (571)272-2198. The examiner can normally be reached on 8:30 AM - 5:00 PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel S. Larkin/
Primary Examiner, Art Unit 2856
03 December 2008